

REMARKS

In the Office Action mailed March 2, 2006, the Examiner has withdrawn the restriction presented in the Office Action dated August 31, 2005; however, election is now required as between allegedly patentably distinct species:

- | | |
|-----------|--|
| Species A | <i>Salmonella typhimurium</i> having a mutation in the <i>asdA3</i> gene; |
| Species B | <i>Salmonella typhimurium</i> having a mutation in the <i>asdA3</i> gene and the <i>thyA</i> gene; |
| Species C | <i>Salmonella</i> having a mutation in the <i>phoP</i> gene; |
| Species D | A derivative of an enteropathogenic bacterium utilizing an <i>asd</i> gene complementation (<i>i.e.</i> , plasmid maintenance) system (see U.S. Pat. No. 5,672,345 for additional details); |
| Species E | <i>Salmonella</i> having a mutation in the <i>cdt</i> gene; |
| Species F | <i>Salmonella choleraesuis</i> having a mutation in the <i>cya</i> and <i>crp</i> genes; and |
| Species G | <i>Salmonella typhi</i> having a mutation in the <i>cya</i> and <i>crp</i> genes. |

The Examiner reasons as follows:

"The species are independent or distinct because the method of delivering a protein wherein the method utilizes different enteropathogenic bacteria having a variety of different functions and abilities. The groups are drawn to different strains of bacterium, and different properties for each bacterium, *i.e.*, some must be live avirulent strains, while other must be a derivative of a pathogenic strain of bacteria. The species of bacterium are also drawn to divergent mutations, such as mutations that affect different genes and different enzymes. Furthermore, each bacterium performs its function based on different mutations, thus the bacterium are structurally and functionally divergent. For instance, only Species B requires an enteropathogenic bacterium *Salmonella typhimurium* strain where there is a mutation in the *asdA3* gene which eliminates aspartic acid semialdehyde dehydrogenase and has the additional mutation of providing for the deletion of the *thyA* gene to impose a thymidine requirement. Moreover, the different enteropathogenic bacteria cause a different effect within the generic method. Therefore, the species are independent and distinct. (Office Action dated March 2, 2006, pages 3-4.)

Applicant agrees that the strains are species which all belong to the following category: “an avirulent derivative of an enteropathogenic bacterium...other than one that causes respiratory disease in birds” as recited in generic linking Claim 1. Additionally, Applicant notes that all the cited strains are known in the art, *i.e.*, ATCC 39961, ATCC 39962, ATCC 67923, ATCC 55117, ATCC 55115, ATCC 53865, ATCC 53866, ATCC 55110, ATCC 55113, ATCC 55119, ATCC 55118, ATCC 67537, ATCC 53681, ATCC 67538, ATCC 53680, ATCC 53678, and ATCC 67813. The differences in the particular bacterium relate to the particular mutations to make the bacterium avirulent. The mutations are neither related to nor essential to the role of the bacterium as a vector in the claimed method of delivering a protein to a domestic bird comprising

administering to the bird in a whole-body spray an effective amount of a live avirulent derivative of an enteropathogenic bacterium comprising a recombinant gene that codes for the expression of the protein, wherein (a) the enteropathogenic bacterium is other than one that causes respiratory disease in birds, (b) the protein is delivered to the bird, and (c) the spray is composed of droplets having a mean diameter of 40-200 microns. (Applicant’s Claim 1).

However, Applicant still objects to the species election. As the Examiner notes in Paragraph 5 of this Office Action:

“Upon the allowance of a generic claim, **applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.**” (emphasis added)

Applicant directs the Examiner’s attention to MPEP §806.04(d), which states:

“Once a claim that is determined to be generic is allowed, **all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim will ordinarily be obviously allowable in view of the allowance of the generic claim**, since the additional species will depend thereon or otherwise include all of the limitations thereof.” (emphasis added)

Once again, Applicant notes that Claim 1, which is generic to all the species set forth in the election requirement, has already been patented in the parent case. *See, e.g.*, US Patent No. 6,866,847.

Applicant notes that already patented Claim 1 is the only independent claim in the claim set, i.e., Claims 2-34 all ultimately depend from Claim 1, therefore fulfilling the requirement “depend from or otherwise require all the limitations of an allowable generic claims as provided by 37 CFR 1.141” therefore entitling the Applicant to examination of the additional species recited in the dependent claims, *as noted by the Examiner in Paragraph 5* of the Office Action. Moreover, as noted in MPEP §806.04(d), all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim **will ordinarily be obviously allowable in view of the allowance of the generic claim**, since the additional species will depend thereon or otherwise include all of the limitations thereof.

At the end of prosecution of the parent case, Applicant properly requested the rejoinder of the remaining dependent claims (which merely specified the particular strains of avirulent enteropathogens encompassed by the allowed main claim) by way of a Rule 312 amendment; however, the Examiner refused to consider the amendment, making the filing of the present divisional necessary. The failure of the Examiner to acknowledge that the particular deposited strains are species of the genus “avirulent derivative of an enteropathogenic bacterium” has caused a double patenting paradox, in that Claim 1 of US Pat. No. 6,866,847 and Claim 1 of the present application have been determined to be directed to separate inventions even though they are identically worded. As previously noted, the Examiner may only resolve this paradox by removing the election requirement and requiring linkage (through a terminal disclaimer) to these claims of the parent case.

Conclusion and Provisional Election

Applicant submits that in view of the foregoing remarks all the claims herein are seen to relate to a single inventive concept, and the claims are in a form and are of the sort that is properly viewed as relating to a single invention. Applicant requests that the election requirement of the Office Action of March 2, 2006 be reconsidered and withdrawn.

Although, for reasons set forth above, Applicant believes that the election requirement is improper and uncalled for, and without in any way acquiescing in the reasons for the requirements set forth in the Office Action, but in order to avoid abandonment for failure to respond, Applicant provisionally elects for examination species D: i.e., the method of Claim 1 practiced with an asd mutant strain having a balanced lethal system for plasmid maintenance.

Respectfully submitted,



Leon R. Yankwich, Reg. No. 30,237
Michael R. Wesolowski, Reg. No. 50,944
Attorneys for Applicants
YANKWICH & ASSOCIATES, P.C.
201 Broadway
Cambridge, Massachusetts 02139
telephone: 617-374-3700
telecopier: 617-374-0055

Certificate of Mailing

The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service under 37 CFR 1.8, postage prepaid, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

April 3, 2006

date



Nasim G. Memon